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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,372	12/21/2001	Roger A. Sabbadini	LPT-3001-UT	3592
35938	7590	04/07/2008	EXAMINER	
Biotechnology Law Group c/o Portfolioip P.O. Box 52050 Minneapolis, MN 55402			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			04/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/029,372	Applicant(s) SABBADINI, ROGER A.	
	Examiner Ralph Gitomer	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment received 2/28/08 has been entered and claims 29-42 are currently pending in this application. In view of the amendments to the claims and arguments presented, the rejections of record under obviousness double patenting and 35 USC 112, second paragraph, are hereby withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Gamble and Tabas in view of Applicant's admissions in the specification in further view of Friedrichs.

Gamble (6,649,362) entitled "Screening Method for an Agent Having an Effect on a Sphingosine Kinase Signaling Pathway" teaches in column 5 last paragraph bridging to column 6, modulating activity of sphingosine kinase pathway can be by competition with substrates such as sphingosine or ATP, interference with the catalytic activity of sphingosine kinase or interfering with enzyme activation. In column 6 lines 29-36, the pathway includes ceramide, Sph-1-P, protein kinase C. In column 7 lines 27-34, modulation is performed by administering an agent to a mammal the modulates synthesis of components, functions as an antagonist or agonist to components of the pathway. In column 11 last full paragraph, the present invention can be used as a

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prophylactic or a therapy for conditions such as coronary heart disease. See the claims.

Tabas (6,613,322) entitled "Method for Treating a Subject Suffering from Conditions Associated with an Extracellular Zinc Sphingomyelinase" teaches in column 8 last paragraph conditions treated include atherosclerotic vascular disease, coronary artery disease, and cerebral vascular disease. In column 9 first full paragraph, the inhibitor may be a peptide or polypeptide, a peptidomimetic compound, an organic compound, a nucleic acid, an inorganic compound or an antibody. The inhibitor inactivates zinc sphingomyelinase.

The claims differ from the above references in that they specify the compounds which inhibit the enzymes.

The specification teaches each of the claimed compounds is known to inhibit the respective enzymes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the claimed compounds to modulate the sphingosine pathway to treat vascular disease in view of the primary references because the specification teaches the claimed compounds are known to modulate the sphingosine pathway. The nexus between vascular disease and the sphingosine pathway is clearly described in the primary references above.

Further, some of the claimed compounds such as sodium fluoride, propranolol, and others are known to be administered to humans for various reasons and treating vascular disease would have been inherent in administering the same compounds for any reason.

The claims as amended further differ from the above references in that they recite the method treats acute myocardial ischemic events.

Friedrichs (US 2002/0150582) entitled "Method of Treating or Inhibiting Cellular Injury or Cell Death" teaches in paragraph 8, the sphingomyelinase pathway can be initiated by the release of TNF and is considered the predominant signaling pathway of the cytokine. This pathway has been demonstrated in cardiac myocytes. Claims 1 and 2 teach treating myocardial infarction or myocardial ischemia by providing a TNF antagonist.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the claimed compounds to treat acute myocardial ischemia because the primary references teach treating coronary artery disease in general which includes both chronic and acute disease and Friedrichs teaches specifically myocardial infarction by inhibiting the sphingomyelin pathway.

Applicant's arguments filed 2/28/08 have been fully considered but they are not persuasive.

Applicant argues that the references do not teach treating acute myocardial ischemia as the claims have been amended to read. And Friedrichs was published after the priority date of this application.

It is the examiner's position that Gamble teaches in column 11 last full paragraph, treating coronary heart disease. And Tabas teaches in column 8 last paragraph treating coronary artery disease. Treating coronary heart disease would encompass all types of coronary heart disease including acute myocardial ischemic events. And Friedrichs teaches inhibiting the sphingolipid pathway to treat myocardial ischemia. Regarding the appropriate date of Friedrichs for the purposes of the above rejection, the application claims priority to 60/240,935 filed 2/10/2000 and so is properly applied.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer
Primary Examiner
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